

## WORLD INTELLECTUAL PROPERTY ORGANIZATION



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> :	A2	(11) International Publication Number:	WO 94/08654
A61M 37/00, 1/60, 1/30 A61C 1/02		(43) International Publication Date:	28 April 1994 (28.04.94)

(21) International Application Number: PCT/US93/09277

(22) International Filing Date: 29 September 1993 (29.09.93)

(30) Priority data: 07/958,931 9 October 1992 (09.10.92) US

(71) Applicant: BIRTCHER MEDICAL SYSTEMS, INC. [US/US]; 50 Technology Drive, Irvine, CA 92718 (US).

(72) Inveators: BEUCHAT, Charles, E.; 6 Westport, Irvine, CA 92720 (US). BURGESS, Vincent, James; 348 30th Street, Hermosa Beach, CA 90264 (US). ETHERINGTON, Roger, F.; 1901 Diana Lane, Newport Beach, CA 92660 (US). RICHARDS, Kent, D.; 21552 Miderest Drive, Lake Forest, CA 92630 (US). WALBRINK, Harold, J.; 52 Coronado Pointe, Laguna Niguel, CA 92677 (US).

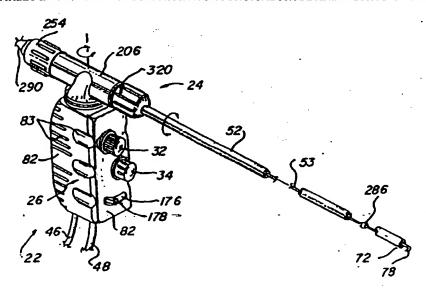
(74) Agents: CRANDELL, Raiph, F. et al.; Holland & Hart, P.O. 8749, 555 17th Street, Suite 2900, Denver, CO 80201-8749 (US).

(81) Designated States: AU, BR, CA, JP, KR, NO, RU, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

**Published** 

Without international search report and to be republished upon receipt of that report.

(54) Title: MINIMALLY INVASIVE IRRIGATOR/ASPIRATOR SURGICAL PROBE AND METHOD OF USING SAME



(57) Abstract

An irrigator/aspirator surgical probe for laparoscopic surgery includes a rotatable handle (22) and a probe (24) having an electrosurgical electrode (78). The handle (22) has two valves (32, 34), one for controlling the flow of irrigation fluid and one for controlling the flow of aspiration fluid. One of the valves can be locked at any selected setting with a locking lever (178). Fine adjustment of the valve is achieved in the locked position. The probe assembly can be rotated relative to the handle assembly as needed to reduce operator fatigue. The probe can be rotated to position the electrode.

5

10

15

20

25

30

35

MINIMALLY INVASIVE IRRIGATOR/ASPIRATOR SURGICAL PROBE AND METHOD OF USING SAME

The present invention relates to laparoscopic surgery and more particularly, to a new and improved minimally invasive surgical probe used to perform surgery and irrigate and aspirate within the interior of the human body.

# Background of the Invention

Three common types of surgery are typically performed internally within the human body. The traditional open type of surgery involves a large incision through the skin and muscle layers of the patient. The incision is made sufficiently large enough both to allow the surgeon to see into the body and to accommodate the surgeon's hands and instruments. Open surgery is sometimes referred to as invasive surgery.

A second type of surgery, endoscopy, involves inserting a flexible instrument through an existing body orifice to gain access to a passageway in the body such as the trachea, colon, or esophagus. The flexible instrument is typically in the form of a tube containing, at a minimum, a light source, an optical sensor, and a surgical tool such as a scalpel, an electrosurgical probe or a laser light channel. Since no incisions are made in the body, endoscopy is referred to as minimally invasive surgery.

A third related type of surgery is laparoscopy which involves cutting one or more small incisions to gain access to an internal cavity such as the abdominal cavity. To perform laparoscopic surgery in the abdominal cavity, two incisions are made through the abdominal wall of the patient. A plastic sleeve or cannula is inserted into both incisions. One cannula is attached to a gas pump, known as an insufflator. The insufflator pumps gas into the abdomen to expand the abdominal wall above the internal organs and create a cavity within which

10

15

20

25

30

35

the surgical procedure is performed. Both cannulas allow instruments to be inserted into the abdominal cavity, manipulated to accomplish the surgical procedure and removed without further injury to the patient's skin and muscle layers. A light source and optical sensor are usually inserted through one of the cannulas. With the light source and sensor, the surgeon watches a video monitor to see the interior of the abdominal cavity. At the conclusion of the procedure, the instruments are removed, the abdominal cavity is deflated and the cannulas are removed. The only remaining outward effects of surgery are the two small incisions. For this reason, laparoscopy is also referred to as minimally invasive surgery.

It is common during minimally invasive surgery to deliver gas or liquid to irrigate the surgical site and wash away debris or other fluid.

Aspiration is also typically used to remove smoke, debris or fluids such as blood or mucus. Aspiration involves suctioning gas, liquid and debris away from the surgical site and out of the body. Irrigation and aspiration are accomplished by placing the distal end of a tube at the surgical site and delivering fluid to the site or sucking fluid or other material away from the surgical site, by creating a positive or a negative pressure at the distal end of the tube, respectively.

The flow of fluid during irrigation and aspiration is typically controlled by the surgeon manually depressing valves which are located in a handle attached to the tube or which are associated with the tube. The tube and the handle are sometimes referred to as the probe. Such valves, which commonly use sliding 0-rings to create seals, have several disadvantages. 0-rings, when not in use, such as during storage and shipping to a

10

15

20

25

30

35

hospital, may become stuck to the surrounding passageway or become flattened thereby causing an ineffective seal. The initial use of an instrument with O-rings may, therefore, be erratic and unsatisfactory. Further, the O-rings may not slide easily, causing difficulty in control and operator fatigue. Debris passing through the valves during aspiration may interfere with proper sealing.

During surgery the surgeon may experience distraction or discomfort from holding the probe in an awkward position or while holding down the valve control buttons on the probe. The relatively long instruments which must be manipulated during minimally invasive surgery may require some degree of added effort and facility to manipulate. surgeon often is required to hold the handle in unusual or uncomfortable positions above the patient while performing the procedure. Holding the valve control buttons in a fixed position for a long period of time may cause discomfort. Since the fingers must firmly hold the control buttons in a fixed position, the instrument cannot be easily shifted around and re-gripped during the procedure, without releasing the control buttons.

Minimally invasive irrigator/aspirator probes may either be reusable or disposable after a single procedure. Disposable instruments are sometimes regarded as desirable because of the inconvenience of having to sterilize the instrument before each use. Autoclaving is the typical method of sterilizing an instrument and it involves placing the instruments in an oven-like device to heat them to an elevated temperature under pressure for a period of time to eliminate all of the bacteria and viruses on or in the instrument. Although disposing of surgical instruments after a single use may be regarded as an unnecessary expense, the autoclaving

10

procedure itself involves the expense of human salary and time. Some surgical instruments are so expensive that they are only available as reusable instruments. Further, some surgical instruments are so complex that they must be disassembled for autoclaving and then reassembled afterwards. The assembly and disassembly procedure also adds to the cost of use of such instruments.

Minimally invasive irrigator/aspirator surgical probes present issues relating to both dispensable instruments and reusable instruments. The complex valve structure which may contain debris from aspiration is particularly difficult to sterilize without time consuming disassembly of the probe.

Other parts of the probe can easily be autoclaved.

It is against this background information, and the desire to produce a more convenient minimally invasive surgical probe, that the present invention has resulted.

20

25

30

35

15

#### Summary of the Invention

The present invention offers many significant improvements for a surgical probe which includes a valve assembly to control the flow of irrigation and/or aspiration fluid through an elongated probe tube. The probe tube is inserted into a body cavity during a laparoscopic surgical procedure and a surgical instrument is inserted through the hollow probe tube to perform a surgical procedure at a surgical site at a distal end of the probe tube. Preferably, the surgical instrument is an electrode by which electrical energy is conducted to the surgical site to achieve electrosurgery.

One of the improvements available from the present invention relates to a handle which extends at a predetermined angle relative to the probe tube. The handle is rotatably connected relative to the probe tube to allow the surgeon to position the

10

15

20

25

30

35

handle in a comfortable and effective position during the laparoscopic surgical procedure. The valve assembly is preferably located in the handle, and the same position of the surgeon's hand relative to the actuation devices which control the valves in the valve assembly is maintained while the handle is rotated.

Another improvement available from the present invention relates to a locking device connected to the handle. The surgeon may selectively engage the locking device with one of the valve members and to hold the valve member in a selected open position. This locking device is preferably used in conjunction with the flow of aspiration fluid. By engaging the locking device, a continual flow of aspiration fluid at the surgical site is available without the discomfort of the surgeon having to continually depress the actuation device associated with the valve.

Another improvement available from the present invention relates to the valve assembly. Preferably, the valve assembly is removable from the handle. With the valve assembly removed, the remaining parts of the surgical probe can be more easily sterilized in an autoclave procedure, for example. The removable valve assembly itself can be disposed of and a new sterile valve assembly inserted in the remaining portion of the surgical probe at the time the surgical probe is again used in a laparoscopic surgical procedure.

A further improvement available from the present invention relates to the use of an elastomeric valve member in the valve assembly. The elastomeric valve member is particularly advantageous in deforming around particles and items of debris which might be lodged in the valve itself. By deforming around the debris, the elastomeric

10

15

20

25

30

35

valve will generally achieve an adequate fluid seal to terminate the flow of irrigation or aspiration fluid, even though a small piece of debris might otherwise prevent full closure of the valve.

A further improvement available from the present invention relates to a rotational capability of the probe tube. The probe tube is preferably attached to a support member which is rotatably connected within a probe body. A connector is operative between the probe body and the support member to selectively permit and prevent rotation of the support member and the connected probe tube. By rotation of the probe tube, the medical instrument extending from the distal end of the probe tube may be more conveniently positioned during the surgical procedure, rather than requiring the surgeon to rotate the whole probe assembly.

Yet another improvement of the present invention is the capability of removing an elongated electrode assembly, when such an assembly is used as the medical instrument within the probe tube. Preferably the electrode assembly includes an elongated electrode to which an insert is connected at a rear end thereof. The insert contacts the support member, and the support member includes an interior channel through which the electrode extends when located within the hollow interior space of the probe tube. A connector, such as the connector which retains the support member and the probe tube to the probe body to permit and prevent relative rotation, may also contact the insert and maintain the electrode assembly in position within the probe.

A more complete understanding and appreciation of the present invention can be obtained by reference to the accompanying drawings, which are briefly described below, from the following detailed

10

15

20

25

30

35

description of the presently preferred embodiment, and from the following claims.

Detailed Description of the Drawings

Fig. 1 is a perspective view showing use of an irrigator/aspirator surgical probe of the present invention in laparoscopic surgery within an abdominal cavity that is shown in a partially broken away illustration.

Fig. 2 is an exploded perspective view of the components of the surgical probe shown in Fig. 1.

Fig. 3 is a perspective view of the surgical probe shown in Figs. 1 and 2.

Fig. 4 is a front elevation view of the surgical probe shown in Fig. 3 with portions broken away.

Fig. 5 is a sectional view taken substantially in the plane of line 5-5 of Fig. 4.

Fig. 6 is a partial sectional view taken substantially in the plane of line 6-6 of Fig. 4.

Fig. 7 is a partial sectional view taken substantially in the plane of line 7-7 of Fig. 6, showing a locking lever in a disengaged position.

Fig. 7A is substantially the same view as Fig. 7, showing the locking lever in an engaged position.

Fig. 8 is an enlarged partial sectional view taken substantially in the plane of line 8-8 of Fig. 7A.

Fig. 9 is a partial sectional view taken substantially in the plane of line 9-9 of Fig. 8.

Fig. 10 is a sectional view taken substantially in the plane of line 10-10 of Fig. 5.

Pig. 11 is an enlarged partial sectional view taken substantially in the plane of line 11-11 of Pig. 10, showing a control valve in a closed, at rest or relaxed position.

5

10

15

20

25

30

35

-8-

Fig. 12 is an enlarged portion of Fig. 5, showing a control valve in an open, stretched position.

Fig. 13 is an enlarged partial sectional view taken substantially in the plane of line 13-13 of Fig. 10, showing a snap pin hidden under a front panel of a handle of the surgical probe.

Fig. 14 is substantially the same view as Fig. 13, showing another arrangement with a snap pin extending through a front panel of a handle of the surgical probe.

Fig. 15 is an exploded perspective view of the surgical probe shown in Figs. 1, 2 and 3, with the handle assembly rotated relative to the probe assembly and illustrating the removable and replaceable nature of the valve assembly using the snap pin arrangement shown in Fig. 14.

Pig. 16 is a perspective view, with a portion broken away, illustrating the distal end of a probe tube of a probe assembly of the surgical probe shown in Figs. 1, 2 and 3.

Fig. 17 is a perspective view similar to that shown in Fig. 16 illustrating a J-hook end formed on an electrode extending from the distal end of the probe tube, as an alternative to the pointed end of a straight electrode shown in Fig. 16.

Fig. 18 is a transverse section view taken substantially in the plane of line 18-18 of Fig. 17.

### Description of the Preferred Embodiment

An irrigator/aspirator surgical probe 20 incorporating the present invention is shown in Figs. 1, 2, 3 and 15 to include a handle assembly 22 and a probe assembly 24. The handle assembly 22 includes a handle 26, a valve assembly 28 having two valves located within a hollow interior 30 (Fig. 5) of the handle 26, two control buttons 32 and 34 which protrude from the handle 26 and which control

10

the operation of the valves of valve assembly 28, a locking lever 36 which may be selectively engaged to keep the control button 34 depressed, and connection ports 38 and 40 on the end of the valve assembly 28 by which to connect the surgical probe 20 to a suction pump 42 and a fluid delivery pump 44 by flexible hoses 46 and 48. The probe assembly 24 includes a probe body 50, a probe tube 52 extending from the probe body 50, an electrosurgical electrode 53 or other elongated medical surgical instrument located within the probe tube 52, and a connection for an electrical cable 54 to the electrode 53.

To use the probe 20, the probe tube 52 is 15 inserted through a cannula 56 placed through a layer 58 of skin and muscle of a patient 60, usually in the abdominal region of the patient, as is shown in Fig. 1. An insufflator (not shown) pumps pressurized gas into the space between the skin and 20 muscle layer 58 and the internal organs 62 to form an internal body cavity 64, typically an abdominal cavity. A combination light source and camera device 66 is inserted through a second cannula 68 placed through the skin and muscle layer 58. The 25 light source of the device 66 illuminates the internal cavity 64 and the camera sends signals to a video monitor (not shown) by which a surgeon 70 can observe the progress of the surgical procedure. With the aid of this light source and camera 30 device 66, the surgeon 70 manipulates the handle assembly 22 to place a distal end 72 of the probe tube 52 at a surgical site 74 and perform the surgical procedure. A third cannula (not shown) is also sometimes used to provide an opening for 35 additional surgical instruments and/or to inflate the internal cavity.

5

10

15

20

25

30

35

During the surgical procedure, it is common for the surgeon to electrosurgically coagulate bleeding sites by applying radio frequency electrical energy from a conventional electrosurgical generator 76 through the cable 54 to the electrode 53. The electrical energy jumps from a distal end 78 of the electrode 53 to the tissue at the surgical site 74 and causes an electrocoagulative effect, as is well known.

It may also be necessary during the procedure for the surgeon to irrigate the surgical site 74 with a liquid or a gas fluid such as sterile saline or air. The irrigation fluid is supplied from the fluid delivery pump 44, conducted through the flexible hose 46, conducted through the valve assembly 28 by depression of one control button 32 or 34, conducted through the probe body 50 and into the probe tube 52, where it is conducted in an annular space 80 (Figs. 3, 5 and 18) between the electrode 53 and the probe tube 52 to the distal end 72 of the probe tube. It may also be necessary to aspirate the surgical site 74. Aspiration is accomplished by depressing the other one of the control buttons 32 or 34 which opens the valve it controls in the valve assembly 28 to a suctioned flow of liquid or gas fluid. The aspirated fluid and debris is carried by the flow of aspirated fluid flow into the distal end 72 of the probe tube 52, along the annular space 80 between the electrode 53, into the interior of the probe body 50, through the valve assembly 28 and the hose 48 to the suction pump 42. Aspiration is frequently applied to remove blood from the surgical site 74, to remove irrigating fluids after they have been applied and to remove smoke in the internal cavity 64 after electrosurgery has been performed.

10

15

20

25

30

35

The handle assembly 22, the probe assembly 24 and the use of the surgical probe 20 are discussed in greater detail below.

As shown in Figs. 2, 3, 5 and 15, the handle assembly 22 includes the handle 26 formed by a housing 82 upon which a grip structure 83 is formed. A front face 84 of the housing 82 has openings formed therein, to allow components of the valve assembly 28 to protrude therethrough. A front panel 86 connects to the housing 82 and continues the structure 83 which the surgeon grips when using the surgical probe 20. The front panel 86 can be snap fitted by conventional tabs and receptacles (not shown) into and out of engagement with the housing 82 to cover the front face 84 of the housing.

The valve assembly 28 is located within the interior of the housing 82, as is best shown in Fig. 5. The valve assembly 28 includes a single valve body 88 which is preferably formed from a plastic material. Located on a bottom face 90 of the valve body 88 are the first and second connection ports 38 and 40, respectively. The connection ports 38 and 40 are connected to the fluid delivery pump 44 and to the suction pump 42 by the hoses 46 and 48 (Fig. 1). The first and second connection ports 38 and 40 communicate with a first and second internal passageway 96 and 98, respectively, formed in the valve body 88. The first and second internal passageways 96 and 98 communicate with a first and second flow port 100 and 102, respectively, located on a top face 104 of the valve body 88, as is also shown in Fig. 10.

A first internal valve bore 106 extends from a front face 108 to a back face 109 of the valve body 88, as is shown in Figs. 5, 10, 11 and 12. The bore 106 intersects the first internal

10

15

20

25

30

35

passageway 96. A first resilient valve member 110 is located in the first valve bore 106. The valve member 110 includes a plug portion 112, a neck portion 114, and a shoulder portion 116 (Pigs. 11 and 12). The plug portion 112 is generally cylindrical except that it has flattened upper and lower surfaces 117 and 118, respectively (Pig. 10). The neck portion is generally cylindrical. The plug portion 112 and the neck portion 114 are located in portions 119 and 120 of the valve bore 106 which are correspondingly shaped in cross-section. The shoulder portion 116 of the valve member 106 engages a lip 122 which surrounds the first internal bore 106 (Fig. 11) at the front face 108. The engagement of the lip 122 and the shoulder portion 116 in the first valve bore 106 prevent movement of the valve member 110 toward the back face 109. A second lip 124, separating the valve bore portions 119 and 120, contacts the plug portion 112 and prevents the plug portion from moving forward out of the valve bore once the valve member 110 is inserted in the valve bore 106. The valve member 110 is trapped in the valve bore by the lips 122 and 124. The first internal passageway 96 intersects the portion 119 of the bore 106 at a position slightly to the rear of the second lip 124, and at the flattened upper and lower surfaces of the valve bore portion 119.

The valve member 110 has an internal center bore 126 along its longitudinal axis, as is shown in Figs. 11 and 12. The bore 126 extends through the shoulder portion 116, the neck portion 114 and partially into the plug portion 112 of the valve. The bore 126 has a slightly larger diameter in the plug portion 112 than in the neck portion 114 and shoulder portion 116 of the valve member 106.

15

20

25

30

35

A valve stem shaft 128 is positioned in the internal bore 126 of the valve member 110, as shown in Figs. 11 and 12. An enlarged head 132 is formed on a rear end of the shaft 128. The enlarged head 132 is located in the enlarged portion of the internal bore 126 in the plug portion 112 of the valve member 110. The valve stem shaft 128 includes a smooth cylindrical portion 136 which extends through the reduced diameter portion of the internal bore 126 that extends through the neck portion 114 and shoulder portion 116 of the valve member 110. A threaded portion 138 of the valve stem shaft 130 extends forward of the smooth cylindrical portion 136. An end cap portion 140 is located on the outermost forward end of the valve stem shaft 128. The threaded portion 138 and the end cap portion 140 extend forward beyond the valve body 88 and through a circular opening 142 in the front face 84 of the housing 82. The control button 32 is attached to the end cap portion 140 of the valve stem shaft 128 on the exterior of the front panel 86. The front panel 86 includes a hole 143 through which the portions 138 and 140 of the valve stem shaft 128 extend. A configuration 145 surrounding the hole 143 allows the button 32 to be depressed.

The resilient valve member 110 is preferably formed of an elastomeric material. The elastomeric properties of the valve member 110 allow it to be stretched, after which it will rebound back to its original shape, thus acting as its own spring. Furthermore, the elastomeric properties of the plug portion 112 of the valve member completely seal against and occlude the openings of the first internal passageway 96 through the valve body 88, thus sealing the passageway 96 and causing the valve

10

15

20

25

30

35

member 110 to act as a fluid sealing device in its relaxed position as shown in Figs. 8 and 11.

The elastomeric properties of the valve 110 also allow the head portion 132 of the valve stem shaft 128 to be inserted through the smaller diameter portion of the bore 126 in the neck portion 114. After the head 132 is inserted to its rearwardmost position in the bore 126, the bore rebounds to its original shape and the valve stem shaft 128 is held in place in the valve member 110. The first control button 32 is press-fitted onto the end cap portion 140 of the valve stem 128.

The length of the first internal bore 106 of the valve body 88 along its longitudinal axis is greater than the length of the valve member 110 (Figs. 5 and 11). At the back face 109 of the valve body 88 a valve body cap 144 seals the rearward end of the internal bore 106 from the outside . environment. When the valve member 110 is in its relaxed position (Fig. 11), a transition region 146 exists between the rearward face of the plug portion 112 and the forward face of the valve body cap 144. The transition region 146 provides room for the plug portion 112 of the valve 110 to move longitudinally in the internal bore 106. The flattened top side 117 and bottom side 118 (Figs. 9 and 10) help to block and seal the internal passageway 96 when the valve member 110 is in the relaxed position (Fig. 11), thus substantially preventing the flow of fluid therethrough.

When the valve stem shaft 128 is moved along its longitudinal axis by operator depression of the control button 32, the elastomeric valve member 110 is stretched longitudinally. As is shown in Fig. 12, most of the stretching takes place in the neck portion 114. The plug portion 112 is moved rearward into the transition region 146. Upon

10

15

20

25

30

35

displacing the plug portion 112 rearwardly from the second lip 124, the plug portion 112 no longer blocks the openings of the passageway 96 into the valve bore 106, and a fluid communication path is established. Fluid can flow through the first internal passageway 96 around the neck portion 114 of the valve member 110. The amount of fluid flow is dependent on the pressure of the fluid source and the size of the opening caused by the amount of rearward movement of the plug portion 112. Thus, the amount of fluid flow can be controlled by the amount of rearward displacement of the valve stem shaft 128 by depressing the button 32.

When the longitudinal force on the valve stem shaft 128 is reduced by releasing the button 32, the elastomeric properties of the valve 110 cause it to rebound back to the relaxed, at rest position (Fig. 8). In the relaxed position, the plug portion 112 has moved forward through the transition region 146 until the forward edge of plug portion 112 again contacts the second lip 124 of the valve bore 106. The flat surfaces 117 and 118 of the plug portion 112 again seal the internal passageway 96 against fluid flow therethrough.

A groove or relief channel 152 is formed in the valve body 88 in a wall 154 of the internal bore 106, as shown in Pigs. 10 and 11. This channel 152 runs longitudinally along the portion 119 of the valve bore 106 in which the plug portion 112 is located. The channel 152 equalizes the fluid pressure on both sides of the plug portion 112 as it moves forward and backward. With this channel 152, the plug 112 can be stretched toward the valve body cap 144 without a resulting increase in air pressure between the valve body cap 144 and the rear end of the valve member 110. Such an increase in air pressure would impede the

WO 94/08654

5

10

15

20

25

30

35

smooth action of the valve member 110. Similarly, the plug portion 112 can easily move forward toward the second lip 124 when the valve member 110 relaxes. The channel 152 is formed in the valve bore 106 between the openings of the passageway 96 into the valve bore and the valve body cap 144. The plug portion 112 of the valve member 110 always contacts the channel 152 to prevent the fluid and debris passing through the passageway 96 from entering the channel 152.

The structure, nature and operation of the first valve member 110, the first internal passageway 96, the first internal valve bore 106, the first valve stem shaft 128, the first channel 152, the first control button 32 and the first valve body cap 144 have been described in detail, and are identical to the structure, nature and operation of a second valve member 160, the second internal passageway 98, a second internal valve bore 162, a second valve stem shaft 164, a second channel 165 (Fig. 9), the second control button 34 and a second valve body cap 166 (Fig. 2), respectively. Accordingly, details of the second valve are described since they are identical with the correspondingly named elements of the first valve.

The first and second internal passageways 96 and 98, respectively, extend generally parallel to each other through the valve body 88, as is shown in Fig. 10. The first and second valve bores 106 and 162 are also generally parallel to each other in the valve body 88, as well as being essentially perpendicular to the passageways 96 and 98. However, the two bores 106 and 162 are vertically offset from one another in their respective positions along the passageways 96 and 98. Further, as shown in Fig. 10, the relief channels 152 and 165

10

15

20

25

30

35

in each of the two bores 106 and 162, respectively, are located to the inside of the valve body 88.

The locking lever 36 is available for holding the second valve in an open or depressed position. As is shown in Figs. 2, 4, 5, 6, 7, 7A and 8, the locking lever 36 is pivotally connected to the front face 84 of the valve body 88 by a pivot shaft 172. One end 174 of the locking lever 36 extends outward through a semicircular shaped slot 176 formed in the front panel 86. The end 174 forms a tab 178 which is accessible to pivot the lever 36 about the pivot shaft 172. Another end 180 of the locking lever 36 has a notch 182 formed in one side facing the threaded portion 138 of the valve stem shaft 164. The internal surface of this notch 182 is threaded at the same pitch as the threads on the threaded portion 138 of the valve stem shaft 164.

When the locking lever 36 is pivoted, the threaded notch 182 engages with the threaded portion 138 of the valve stem shaft 164, and the valve stem shaft is held in this position. The valve member 160 may be held at any position to which it has been depressed by the locking lever 36, thereby establishing a fixed open setting for the valve. The surgeon is relieved of maintaining pressure on the button 34. The button 34 and valve stem shaft 164 can be turned to finely adjust the open position of the second valve, because the valve stem shaft 164 will rotate in the bore 162 in the valve member 160. The flat sides 117 and 118 (Fig. 10) of the valve member 160 prevent it from rotating in the valve bore 162. When the operator disengages the locking lever 36 by moving the tab 178 to pivot the lever and move the threaded notch 182 away from the threaded portion 138 of the valve stem shaft 164, the valve member 110 is free to operate as previously described.

WO 94/08654

5

10

15

20

25

30

35

Thus, the surgeon can actuate the valve member 160 to a desired position, lock that position with the locking lever 36 and then make further adjustments as necessary. Alternatively, the surgeon can begin by pivoting the locking lever 36 to hold the valve member 160 in the closed position and then turn the valve stem shaft 164 and button 34 until the desired open position is achieved.

The valve body 88 is held in place in the handle 26 by a snap pin 184 inserted through an opening 185 in the front face 108 of the housing 82 and into a pin receptacle 186 in the valve body 88, as is shown in Figs. 13, 14 and 15. When the valve stem shafts 110 and 160 and the snap pin 184 are removed, the valve body 88 is no longer attached to the housing 82. The valve body 88 then can be easily removed through an open bottom end 188 (Fig. 5) of the housing, as is illustrated in Fig. 15.

Figs. 13 and 14 show two alternative arrangements for holding the valve body 88 using the snap pin 184. In one arrangement (Fig. 13) a head 190 of the snap pin 184 is hidden under the front panel 86. This arrangement is preferably used when the entire probe 20 including the valve body 88 will be disposed of after each surgical use. When the probe is disposable, as many of the other components of the surgical probe as realistically possible will be formed from low-cost plastic. In the other arrangement (Fig. 14) a hole 192 is formed through the front panel 86 and the snap pin 184 is inserted through the opening 185 and into the receptacle 186 of the valve body 88. The head 190 of the snap pin is visible and accessible from the exterior of the handle assembly 22. This arrangement is used where it is desirable to remove, dispose of and replace the valve body 88 after each

10

15

20

25

30

35

use. The remainder of the surgical probe must be sterilized before subsequent use. Where the valve body is disposable and the remaining portions of the surgical probe are re-useable, the present invention will usually have many non-disposable components, other than the valve body 88, which are able to withstand sterilization.

A confluence chamber member 194 is attached, preferably by a sealing adhesive, to the top face 104 of the valve body 88, as is shown in Figs. 2, 5, 10 and 15. The confluence chamber 194 establishes a common communication channel between the two internal passageways 96 and 98 of the valve body 88 and an upper opening 196 formed in the confluence chamber 194. Fluid communication with the probe assembly 24 is established through the opening 196. An O-ring seal 198 is attached surrounding the opening 196 on a neck portion 199 of the confluence chamber 194. The O-ring 198 seals the confluence chamber 194 to the probe body 50 of the probe assembly 24. The confluence chamber 194 conducts the gas and liquid fluid delivered through the valves during irrigation and aspiration of the surgical site, as determined by the surgeon's actuation of valves by the control buttons 32 and 34.

The fluid conducted from or to the confluence chamber during irrigation and aspiration enters and leaves from an interior chamber 202 of the probe body 50, as shown in Fig. 5. The interior chamber 202 of the probe body communicates with the annular space 80 between the probe tube 52 and the electrosurgical electrode 53 or some other surgical instrument, such as a gas-assisted electrosurgical tubing and nozzle assembly, a surgical laser optical bundle or a mechanical surgical instrument, for example (none of which are shown).

5

10

15

20

25

30

35

-20-

The probe body 50 of the probe assembly 24 includes a T-shaped housing 206, as shown in Figs. 2, 5 and 15. The housing 206 includes a port 208 which engages with and fits within the handle assembly 22. On the exterior of the port 208 is a resilient lip 210 which snaps into engagement with a lip 212 in an upper opening 213 of the housing 82 (Fig. 5). An 0-ring 214 is located on the exterior of the port 208 to engage with and seal against the housing 82 at the opening 213.

An integral sleeve 216 (Fig. 5) of the T-shaped housing 206 is located in the interior of the port 208 and extends toward the handle assembly. The sleeve 216 engages the 0-ring 198 on the neck portion 199 of the confluence chamber 194 to establish the primary seal between the handle assembly 22 and the probe assembly 24. The Oring 214 between the port 208 and the housing 82 functions as a secondary seal to prevent leakage between the handle assembly and the probe assembly. Once the T-shaped housing 206 is connected in place on the handle housing 82, the housing 206 may be rotated freely relative to the handle assembly 22, as shown in Fig. 15, since the O-rings 198 and 214 permit this relative rotational movement while maintaining the seal between the handle assembly and the probe assembly.

The hollow interior of the sleeve 216 is part of the interior chamber 202 of the housing 206 and communicates with the interior of the confluence chamber 194. The interior chamber 202 of the T-shaped spool housing 206 also includes a large, internal bore 220 through which many of the remaining components of the probe assembly 24 are attached to and within the spool housing 206.

A cylindrical electrode spool 240 is inserted into a front end 242 of the internal bore 220 of the

10

15

20

25

30

35

housing until an annular protruding lip 244 near a front end 246 of the electrode spool 240 abuts a ring-shaped front face 248 of the spool housing 206, as is shown in Figs. 2 and 5. In this position, a rear end 250 of the electrode spool 240 protrudes slightly rearwardly outward from the internal bore 220 beyond a rear face 252 of the spool housing 206.

The spool 240 is held in this position by a nut 254 which is threaded on an external thread 256 that is formed on the rear end 250 of the electrode spool 240. A lip 258 extends inwardly at the open rear end of the housing 206. The nut 254 includes a forward projecting internal sleeve 260. An outer projecting annular ring 262 is located on the forward end of the sleeve 260, and the ring 262 is forced forward past the lip 258 to snap fit the nut 254 to the rear end of the housing 206. The snap fit between the lip 258 and the ring 262 and sleeve 260 allows the nut 254 to freely rotate in its attachment to the rear of the spool housing 206. When the nut 254 is loosely tightened on the threads 256 of the electrode spool 240, a slight axial tolerance exists between the protruding lip 244 near the front end of the spool and the front face 248 of the housing 206 and/or between the nut 254 and the rear face 252 of the housing 206. This axial tolerance allows rotation of the electrode spool 240 relative to the housing 206.

Integrally formed into an outer surface 263 of the electrode spool 240 are a first and a second pair of support collars 264. When the electrode spool 240 is located in the spool housing 206, the support collars 264 are located near each end of the spool housing 206. The support collars contact a cylindrical wall internal bore 220 of the housing 206. Due to the relatively smooth surface

5

10

15

20

25

30

35

-22-

of the internal bore 220 and the outer circular shape of the support collars 264, the electrode spool 240 may also freely rotate within the internal bore of the spool housing on the support collars 264.

The electrode spool 240 has a hollow interior channel 270 formed axially through the spool 240. The interior channel 270 is formed in three generally cylindrically shaped sections. A rear section 272 of the channel 270 has the largest diameter of the three sections. A center section 274 of the channel 270 has the smallest diameter of the three sections. A front section 276 of the channel has a diameter larger than the center section 274 and smaller than the rear section 272. The probe tube 52 has an outer diameter sufficient to snugly fit within the diameter of the front section 276 of the channel 270. The probe tube 52 is formed of a poltruded, non-conductive, composite material, and is connected to the front section 276 of the internal channel 270 as shown in Fig. 5, preferably with an adhesive.

Two communication ports 278 and 280 are formed in the spool 240 between the pairs of support collars 264 and extend from the outer surface 263 of the spool to the center section 274 of the interior channel 270, as is shown in Figs. 2 and 5. The communication ports 278 and 280 establish a communication path between the interior chamber 202 of the spool housing 206 and the interior channel 270 of the electrode spool 240. An Oring 282 is placed between each of the two pairs of support collars 264 to establish a seal between the exterior of the spool 240 and the internal bore 220 at the location of the support collars 264. The seals established by the Orings 282 are located in front of and behind the location where the

5

10

15

20

25

30

35

sleeve 216 opens from the interior chamber 202 into the opening 196 of the confluence chamber. As a result, the fluid communication to and from the handle assembly 22 through the confluence chamber 194 is confined to the interior chamber 202 between the 0-rings and to the interior channel 270 of the spool through the communication ports 278 and 280.

The electrode 53 is preferably inserted into the electrode spool 240 as is shown in Figs. 2, 5 and 15. Preferably, the electrode 53 is a solid, elongated and stiff electrical conductor with a tip 284 having a needle or some other configuration (Figs. 16 or 17) at its distal end, although a gas conducting tubing with a nozzle and electrode assembly such as that employed in gas assisted electrocoagulation, described in U.S. Patent No. 4,781,175, could also be employed. The electrode 53 is maintained in a centered position relative to the non-conductive probe tube 52 by an enlarged flat portion 286 (Fig. 16) formed near its distal end. The flat portion 286 contacts the inside of the probe tube 52 and holds the distal end of the electrode 53 in a centered position relative to the distal end 72 of the probe tube, as is shown in Fig. 18. Since the rear end of the electrode 53 is also maintained in an axially centered position in the electrode spool as explained below, the electrode 53 extends coaxially along the probe tube 52 and through the probe assembly 24.

Attached to the rear of the electrode 53 is a female receptacle tube 288 which receives a male banana-clip electrical connector 290 connected to the end of a cable 54 from the electrosurgical generator 76, as is shown generally in Figs. 1 and 3 and more specifically in Figs. 2, 5 and 15. The hollow receptacle tube 288 slips over, and is

15

20

25

30

35

electrically connected with (preferably by soldering) the rear end of the electrode 53 (Fig. 5). Mechanically attached near the rear end of the electrode 53 and in front of the tube 288 is a collar 294. The collar 294 includes a radially extending slot 296 (Pigs. 2 and 15) to allow the collar 294 to be placed over the tube 288 from the side. The collar 294 has an enlarged end receptacle 298 (Fig. 5) in which to receive a reduced diameter sleeve portion 300 of an insert 302. The insert 302 is positioned over the tube 288 from the rear and attached thereto, preferably by an adhesive. An O-ring 304 is positioned over the sleeve portion between a forward facing shoulder of the insert and a rearward facing end surface of the collar 294. The electrode 53, the receptacle tube 288, the collar 294, the insert 302 and the O-ring 304 make up an electrode assembly 310 (Fig. 2).

The electrode assembly 310 is inserted into the rear of the channel 270 of the electrode spool 240 until a protruding lip 312 on the insert 302 abuts the rear end of the spool 240, as is shown in Fig. 5. Thereafter the electrode spool 240 is inserted into the internal bore 220 from the front end of the spool housing 206. The nut 254 is threaded onto the threads 256 at the rear end of the electrode spool 240. A forward facing shoulder 313 on the nut 254 contacts the lip 312 and holds the insert 302 and hence the electrode assembly 310 in place relative to the electrode spool 240. As the nut 254 is tightened more, the electrode spool is drawn to the rear, and the lip 244 contacts the front face 248 of the spool housing 206, thus also holding the electrode spool 240 and the electrode assembly 310 firmly in place in the spool housing 206.

10

15

20

25

30

35

The collar 294 and the cylindrical portion of the insert 302 in front of the lip 312 and behind the sleeve portion 300 fit snugly into the rear section 272 of the interior channel 270 to locate the electrode 53 axially within the interior channel of the electrode spool 240, as is shown in Fig. 5. Further forward movement of the electrode assembly 310 relative to the electrode spool 240 is prevented by contact of the front end of the collar 294 against the shoulder of the electrode spool at the transition from the rear section 272 to the center section 274 of the interior channel 270. The axial force applied from the nut 254 to the insert 302 is transferred through the 0-ring 304 to the collar 294 and to the electrode spool 240. The O-ring 304 between the insert 302 and the collar 294 is slightly compressed to establish a seal with the wall of the rear section 272 of the interior channel, thereby preventing gas and liquid from exiting from the rear of the probe assembly 24. Held together in this manner, the needle tip 284 of the electrode 53 is located at a predetermined position relative to the distal end 72 of the probe tube 52.

Tightening of the nut 254 on the electrode spool 240 will firmly restrain the electrode spool against the spool housing 206, thus substantially preventing the electrode spool and electrode assembly 310 from rotating about their longitudinal axes. Of course, when the locking nut is loosened, the electrode spool and the electrode assembly can be freely rotated. Eight raised longitudinal ridges 318 on the exterior of the nut 254 aid in grasping and turning the nut.

A knob 320 is attached to the front end 246 of the electrode spool 240 to allow the surgeon to easily and conveniently turn the spool 240 and the

5

10

15

20

25

30

35

-26-

electrode assembly 310 relative to the spool housing 206. The knob 320 is formed as a cap-like structure having an interior shape to slide over and fit on the bulbous front end 246 of the electrode spool, as is shown in Figs. 2, 5 and 15. A pair of diametrically opposed and outward protruding longitudinal ridges 322 are formed on the outer surface of the bulbous front end 246. Two longitudinal grooves 324 are formed in the interior of the knob 320 to mate and engage with the longitudinal ridges 322 on the front end of the electrode spool 240. An annular ridge 326 is also formed on the bulbous front end 246. The annular ridge 326 lies in a plane parallel to and slightly forward of the protruding lip 244 on the front end 246 of the electrode spool. An annular ring groove 328 extends into the interior of the knob 320. The ring groove 328 is located at a position which mates and engages with the annular ridge 326 on the electrode spool when the knob 320 is pressed on to the front end 246 of the electrode spool. The mating engagement of the ring groove 328 and the annular ridge 326 prevents the knob 320 from easily disengaging with the front end 246 once it has been snapped on. The mating engagement of the longitudinal ridges 322 and grooves 324 allows torque applied to the knob to be transferred to the electrode spool. The knob 320 preferably has eight raised, longitudinal ridges 330 to assist in grasping and turning the knob 320.

To use the surgical probe 20, it is connected to the electrosurgical generator 76 with the cable 54 and the connector 290, as is shown in Fig. 1. The surgical probe is also connected to a source of suction such as the suction pump 44 and to a source of fluid such as the fluid delivery pump 42. The valves are used to control the

10

15

20

25

30

35

delivery of fluid for irrigation and the application of suction for aspiration. The surgeon twists the handle assembly 22 relative to the probe assembly 24 until a comfortable position is achieved. distal end 72 of the probe tube 52 is located at the desired surgical site. The buttons 32 and 34 are depressed to irrigate or aspirate the surgical site. The electrosurgical generator 76 is energized to deliver RF electrical energy through the electrode 53 and thereby create an

electrocoagulative effect at the surgical site 74.

The valve members 110 and 160 are elastomeric and their inherent resiliency acts as a return spring and as an effective seal. The self returning aspects of the valves are important in reducing the number of working parts and potential sources of mechanical failure. The resiliency achieves a good fluid seal even when small pieces of debris move through the valve assembly. Should a small piece of debris be trapped at one of the openings to the internal passageways 96 and 98 when the valve is closed, the resilient material of the valve member is usually successful in deforming around the debris and still establishing an effective seal.

Further, one of the valves can be locked in any selected position by actuation of the locking lever 36. Fatigue and discomfort to the surgeon is avoided because the surgeon is relieved of the task of continually depressing the control button for the valve. Very precise regulation of the degree of opening or closing of the valve is also attainable because of the threaded engagement of the locking lever 36 and the threaded portion 138 of the valve stem shaft.

Part of the surgical probe 20 can be made reusable by allowing the valve assembly 28 to be removed and disposed of while another new valve

5

10

15

20

25

30

assembly can be inserted after the remaining portions of the probe have been sterilized. Thus, the probe need not be made wholly reusable or wholly disposable, although the construction of the probe admits to convenient disposable construction.

Due to the rotatable connection of the probe assembly 24 and the handle assembly 22, the probe assembly can be freely rotated about the handle assembly. The surgeon can twist the handle assembly 22 relative to the probe tube 52, as shown in Fig. 1, to maximize comfort, provide for right handed and left handed use of the probe, and achieve better control over the conduct of the surgical procedure.

The electrode spool 240 and thus the electrode 53 may be rotated about their longitudinal axes by loosening the locking nut 254 and twisting the electrode spool knob 320 as necessary. The surgeon is able to adjust the position of a non-symmetrical electrode, such as a j-hook electrode.

By removing the locking nut 254, the entire electrode assembly 310 can be easily removed from the probe assembly 24. This allows the surgeon to change to different types of electrodes while using only one probe tube.

A presently preferred embodiment of the present invention has been described above with a degree of specificity. It should be understood, however, that this degree of specificity is directed toward the preferred embodiment. The invention itself is defined by the scope of the following claims.

10

15

20

25

30

35

#### THE INVENTION CLAIMED IS:

 An irrigator/aspirator surgical probe comprising:

an elongated hollow probe tube having an interior space through which irrigation and aspiration fluid flows to and from a surgical site; and

a handle extending at a predetermined angle from the probe tube and rotatably connected relative to the probe tube to allow the handle to rotate about an axis extending at the predetermined angle from the probe tube.

- 2. A surgical probe as defined in claim 1 wherein the predetermined angle is substantially perpendicular.
- 3. A surgical probe as defined in claim 1, further comprising:

an actuation device located on the exterior of the handle to control the application of at least one of the irrigation and aspiration fluid flow through the probe tube.

- 4. A surgical probe as defined in claim 3 wherein the actuation device is connected to the handle to rotate in unison with the handle.
- 5. A surgical probe as defined in claim 3 further comprising:

a valve assembly located within the handle and operative for controlling the flow of fluid through the probe tube, the valve assembly including means for connecting the valve assembly to one of a source of irrigation or aspiration fluid; and wherein:

the valve assembly includes a valve member moveable between a closed position where the fluid flow within the probe tube is terminated and an open position where the fluid flow is established; and

10

15

20

25

30

35

the actuation device is operatively connected to the valve member to move the valve member from the closed position to the open position.

- 6. A surgical probe as defined in claim 5 further comprising:
- a locking device connected to the handle and selectively operative to hold the valve member in an open position.
- 7. A surgical probe as defined in claim 6 further comprising:

a valve stem shaft connected to the valve member and operative for moving the valve member between the open and closed positions, the valve stem shaft extending from the valve assembly to the exterior of the handle; and wherein:

the actuation device includes a control button connected to an end of the valve stem shaft at the exterior of the handle;

the locking device contacts the valve stem shaft to maintain the position of the valve stem shaft; and

the locking device includes selecting means extending from the handle for selectively positioning the locking device into contact with the valve stem shaft.

- 8. A surgical probe as defined in claim 7 wherein the valve assembly, the valve member, the valve stem shaft, the control button and the locking device all rotate in unison with the handle.
- 9. A surgical probe as defined in claim 7 wherein:

the valve assembly is removable from the handle to allow selective replacement of the valve assembly after use; and

WO 94/08654

5

10

15

20

25

30

the valve stem shaft is disconnectable from the valve member to allow the valve assembly to be removed from the handle.

- 10. A surgical probe as defined in claim 5 wherein the valve member is formed of elastomeric material.
- 11. A surgical probe as defined in claim 5 wherein:

the handle includes an opening through which the fluid flows from the valve assembly; and further comprising:

a probe housing connected to the probe tube and supporting the probe tube to extend from the probe housing, the probe housing having an interior chamber in fluid communication with the interior space in the hollow probe tube, the probe housing also including a port which communicates with the interior chamber of the probe housing; and

a rotational connection between the handle and the probe housing and operative for aligning the port and the opening in the handle to maintain fluid communication therebetween.

- 12. A surgical probe as defined in claim 11 further comprising:
- a confluence chamber connected to the valve assembly and extending through the opening and into the port of the probe housing;
- a sleeve extending from the probe housing at the port and into the opening in the housing, the sleeve extending into adjacency with the confluence chamber, the fluid communication with the interior chamber of the probe assembly occurring through the confluence chamber and the sleeve; and
- a sealing member positioned between the
  confluence chamber and the sleeve to seal the fluid
  flow between the confluence chamber and the interior
  of the probe housing.

PCT/US93/09277

5

10

15

20

25

30

35

13. A surgical probe as defined in claim 12 further comprising:

a second sealing member in addition to the sealing member first aforesaid, the second sealing member positioned between the probe housing and the handle at a location adjacent the port and the opening in the housing.

- 14. A surgical probe as defined in claim 1 wherein the probe tube extends along an axis, and the probe tube is connected to the handle to allow selective rotation about the axis through the probe tube.
- 15. A surgical probe as defined in claim 1 wherein:

the probe tube extends to a distal end which is adapted to be positioned at a site where the surgical procedure is performed, and further comprising:

means for supporting a surgical instrument within the hollow probe tube and extending from the distal ends of the tube, the support and size of the surgical instrument allowing a space between the probe tube and the surgical instrument for the flow of fluid, the supporting means further allowing removal of the surgical instrument from within the probe tube.

16. A surgical probe comprising:

an elongated probe tube through which at least one of irrigation or aspiration fluid flows to and from a surgical site;

a handle connected to the probe tube to allow manipulation of the probe by the handle during a surgical procedure;

a valve assembly located within the handle and operative for controlling the flow of fluid through the probe tube, the valve assembly including means adapted for connecting the valve assembly to

10

15

20

30

at least one source of irrigation or aspiration fluid;

the valve assembly includes a valve member moveable between a closed position where the fluid flow within the probe tube is terminated and an open position where the fluid flow is established to the source of irrigation or aspiration fluid; and

- a locking device connected to the handle and selectively moveable by the surgeon to hold the valve member in an open position.
- 17. A surgical probe as defined in claim 16 wherein:

the locking device is movable between a holding position where the valve member is held in the position it occupied when the locking device was moved into the holding position and a free position where movement of the valve member is not inhibited by the locking device; and

the locking device includes a tab-like portion which protrudes to the exterior of the handle and which is contactable to move the locking device between the holding and the free positions.

- 18. A surgical probe as defined in claim 17 further comprising:
- a shaft connected to the valve member and operative for moving the valve member between the open and closed positions, the valve stem shaft extending from the valve assembly; and wherein:

the locking device contacts the shaft in the holding position to maintain the position of the shaft.

19. A surgical probe as defined in claim 18 wherein:

the shaft has an externally threaded region in which it is contacted by the locking device; and

10

15

20

25

30

35

the locking device includes a threaded portion which contacts the threaded region of the shaft when the locking device is positioned in the holding position.

20. A surgical probe as defined in claim 19 wherein:

the threads on the threaded region mesh with the threads on the threaded portion of the shaft;

the engagement of the threaded portion and the threaded region allows rotation of the shaft to establish longitudinal movement of the shaft while the locking portion is in contact with the shaft when the locking device is in the holding position;

the shaft extends to the exterior of the handle to allow the shaft to be rotated; and longitudinal movement of the shaft moves the valve member.

21. A surgical probe as defined in claim 19 wherein:

the locking device includes a locking
lever which is pivotably connected to the housing;
the locking lever includes a notch which
contacts the threaded portion of the shaft and which
forms the threaded portion of the locking device;
and

the locking lever includes the tab-like portion.

22. A surgical probe as defined in claim 18 wherein:

the valve assembly is removable from the handle to allow selective replacement of the valve assembly after use; and

the shaft is disconnectable from the valve member to allow the valve assembly to be removed from the handle.

5

10

15

20

25

30

35

-35-

23. For use with a surgical probe comprising an elongated hollow probe tube having an interior space through which at least one of irrigation or aspiration fluid flows to and from a surgical site at a distal end of the probe tube, a handle operatively connected to the probe tube to allow manipulation of the probe by the handle during a surgical procedure, the surgical probe for use with at least one of a source of irrigation fluid or a source of aspiration fluid; a valve assembly comprising:

a valve body adapted to be retained in a hollow portion of the handle and operative for controlling the flow of fluid through the probe tube from one of a source of irrigation or aspiration fluid;

fluid connection means adapted for connecting the valve assembly to the source of irrigation or aspiration fluid;

an internal passageway formed in the valve body and communicating with the source of irrigation or aspiration fluid and with the hollow interior of the probe tube;

a valve bore formed in the valve body and intersecting the passageway;

a valve member positioned in the valve bore and moveable to a closed position where the valve member blocks fluid flow through the passageway and moveable to an open position where the valve member allows fluid flow through the passageway; and

means connected to the valve body and interacting with the handle for selectively retaining the valve body in position in the handle and for selectively releasing the valve body from the handle for removal after use of the surgical probe.

10

15

20

25

30

35

24. An invention as defined in claim 23 wherein the valve assembly is used with a valve stem shaft of the surgical probe through which force is applied to control the movement of the valve member to the open and closed positions, and wherein:

the valve member includes means adapted for connecting to the valve stem shaft and for disconnecting from the valve stem shaft to allow removal of the valve assembly from the handle.

25. An invention as defined in claim 24 wherein the valve stem shaft includes a head portion and a smaller shaft portion adjoining the head portion, and wherein:

the means adapted for connecting to and disconnecting from the valve stem shaft comprises a shaft-receiving bore formed into the valve member; and

the shaft-receiving bore includes an inner portion for receiving the head portion of the valve stem shaft, and the shaft-receiving bore also includes a smaller outer portion for receiving the smaller shaft portion of the valve stem shaft.

26. An invention as defined in claim 25 wherein:

the valve member is formed of elastomeric material; and

the elastomeric material surrounding the smaller outer portion of the shaft-receiving bore distorts to allow the head portion of the valve stem shaft to be inserted into and removed from the shaft-receiving bore.

27. An invention as defined in claim 26 wherein:

the elastomeric material of the valve member surrounding the smaller outer portion of the shaft-receiving bore retains the valve stem shaft in

10

15

20

25

30

35

the shaft-receiving bore during use of the valve assembly.

28. An invention as defined in claim 25 for a surgical probe for use with a source of irrigation fluid and a source of aspiration fluid, the probe further comprising a probe body connected to the handle and having an interior chamber in fluid flow communication with the interior space within the hollow probe tube; and the valve assembly further comprising:

a second internal passageway formed in the valve body in addition to the internal passageway first aforementioned;

the first passageway communicating with the source of irrigation fluid and with the hollow interior of the probe tube;

the second passageway communicating with the source of aspiration fluid and with the hollow interior of the probe tube;

a second valve bore formed in the valve body in addition to the valve bore first aforementioned;

the first valve bore intersecting the first passageway;

the second valve bore intersecting the second passageway;

a second valve member in addition to the valve member first aforementioned;

the first valve member positioned in the first valve bore and moveable to a closed position where first valve member blocks fluid flow through the first passageway and moveable to an open position where the first valve member allows fluid flow through the second passageway;

the second valve member positioned in the second valve bore and moveable to a closed position where second valve member blocks fluid flow through

PCT/US93/09277

5

10

15

20

25

30

35

the second passageway and moveable to an open position where the second valve member allows fluid flow through the second passageway;

the valve members each include means adapted for connecting to and disconnecting from a valve stem shaft through which force is applied to control the movement of the valve member to the open and closed positions; and

- a confluence chamber connected to the valve body and communicating the flow of fluid between the first and second passageways and the interior chamber of the probe housing.
- 29. An invention as defined in claim 23 wherein the probe further comprises a probe body connected to the handle and having an interior chamber in fluid flow communication with the interior space within the hollow probe tube, the valve assembly further comprises:
- a confluence chamber connected to the valve body and communicating the flow of fluid between the passageway and the interior chamber of the probe body.
- 30. An invention as defined in claim 29 wherein:

the confluence chamber includes a neck portion having an opening therethrough by which fluid is communicated between the passageway and the interior chamber of the probe housing, and a sealing member connected to the neck portion by which to seal the confluence chamber to the probe housing and to seal the fluid communication passageway between the first and second passageways and the interior chamber of the probe body.

31. An invention as defined in claim 30 wherein the handle is rotatably connected to the probe housing, and wherein:

15

20

25

30

35

the sealing member maintains the seal between the neck portion of the confluence chamber and the probe body upon rotation of the handle relative to the probe body.

- 32. An irrigator/aspirator surgical probe comprising:
- a handle assembly adapted to be gripped to manipulate said probe during a surgical procedure; and
- a probe assembly connected to the handle, the probe assembly comprising:
  - a probe body including a housing having a bore formed therethrough;
  - an elongated hollow probe tube having an interior space through which irrigation and aspiration fluid flows to and from a surgical site;
    - a support member rotatably connected within the bore of the housing and connected to the probe tube to support the probe tube extending from the support member; and
    - a connector operatively connected between the support member and the housing to selectively permit and to selectively prevent rotation of the support member and the connected probe tube relative to the housing.
    - 33. A surgical probe as defined in claim 32 further comprising:
    - a valve assembly located within the handle assembly, the valve assembly including means for connecting the valve assembly to a source of irrigation or aspiration fluid, the valve assembly further comprising an actuation device operative to control the flow of fluid from the irrigation or aspiration source; and wherein:
  - the housing has an interior chamber, the bore extends through the interior chamber, and the

5

10

20

25

30

35

-40-

interior chamber is in fluid communication with the valve assembly; and

the support member has an interior channel which is in fluid communication with the interior space of the probe tube and with the interior chamber of the housing.

34. A surgical probe as defined in claim 33 wherein:

the probe tube is connected at one end thereof to the support member; and

the interior channel of the support member and the interior space of the probe tube communicate with one another at the connection of the probe tube to the support member.

15 35. A surgical probe as defined in claim 33 further comprising:

a seal positioned between the housing and the support member and operative to confine fluid flow within the interior chamber between interior channel and the handle assembly.

36. A surgical probe as defined in claim 33 wherein:

the support member comprises and elongated spool member having threads formed at one end thereof and a shoulder formed at the other end thereof:

the probe tube is connected to the other end of the spool member;

the connector comprises a nut having threads, and the nut is threaded onto the threaded end of the spool member; and

rotation of the nut on the spool member restrains the housing between the shoulder and the nut to prevent rotation of the spool member relative to the housing.

37. A surgical probe as defined in claim 33 further comprising:

20

25

30

35

an elongated electrode positioned within the interior space of the hollow probe tube and through which electrical energy is applied from a distal end of the electrode to achieve electrosurgical coagulation at a surgical site proximate to a distal end of the probe tube; and wherein:

the elongated electrode extends through the interior channel in the support member; and

a proximal end of the electrode is accessible at the support member by which to conduct electrical energy to the electrode.

38. A surgical probe as defined in claim 37 wherein:

the electrode is removably retained within the support member and the probe tube.

39. An irrigator/aspirator surgical probe comprising:

a handle assembly adapted to be gripped to manipulate said probe during a surgical procedure; and

a probe assembly connected to the handle, the probe assembly comprising:

a probe body including a housing having a bore formed therethrough;

a support member connected to the housing and positioned within the bore of the housing, the support member having an interior channel formed therethrough;

an elongated hollow probe tube having an interior space through which irrigation and aspiration fluid flows to and from a surgical site at a distal end of the probe tube, a proximal end of the probe tube connected to the support member;

an elongated electrode removably positioned within the interior channel of the support member and extending through the interior

5

10

15

20

25

30

35

-42-

space of the hollow probe tube to a distal end from which electrical energy is applied to achieve electrosurgical coagulation at the surgical site, a proximal end of the electrode is accessible at the support member by which to conduct electrical energy to the electrode; and

the electrode is selectively removable from within the interior channel of the support member and from within the interior space of the probe tube.

40. A surgical probe as defined in claim 39 further comprising:

a connector operatively connected to the support member to retain the electrode in position within the interior channel and the interior space.

41. A surgical probe as defined in claim 40 wherein:

the connector is further operatively connected to retain the support member to the housing.

42. A surgical probe as defined in claim 40 further comprising:

an insert connected adjacent to the proximal end of the electrode, the insert contacting the support member when the connector retains the electrode in position.

43. For use with an irrigator/aspirator surgical probe of the type comprising a probe assembly a probe body having a support member with an interior channel formed therethrough, an elongated hollow probe tube having a proximal end connected to the support member and further having an interior space along the tube through which irrigation and aspiration fluid flows to and from a surgical site at a distal end of the probe tube;

PCT/US93/09277

5

10

15

20

25

30

35

an electrode assembly adapted to be selectively removed from the surgical probe, comprising:

an elongated electrode adapted to be positioned within the interior channel of the support member and extending through the interior space of the hollow probe tube to a distal end from which electrical energy is applied to achieve electrosurgical coagulation at the surgical site at the distal end of the probe tube;

an electrical connector connected to the proximal end of the electrode and adapted to be accessible at the support member by which to conduct electrical energy to the electrode;

an insert connected adjacent to the proximal end of the electrode and having a retention portion adapted for contacting the support member and by which retaining force is applied to retain the electrode assembly in position in the probe.

44. An invention as defined in claim 43 wherein the electrode assembly further comprises:

a seal connected to the insert and adapted to establish a fluid seal between the insert and the probe body to prevent the leakage of irrigation or aspiration fluid between the electrode assembly and the probe body at the support member adjacent the electrical connector.

45. An invention as defined in claim 43 wherein the surgical probe further includes a nut threaded onto the support member for retaining the electrode assembly to the support member, and wherein:

the retaining portion of the insert comprises a lip adapted for contact retention between the support member and the nut by which to retain the electrode assembly in position in the surgical probe.

10

15

20

25

30

35

46. A method of removing debris from a surgical site during laparoscopic surgery, comprising the steps of:

positioning a distal end of a hollow probe tube at a surgical site;

conducting a flow of aspiration fluid from the surgical site through an interior space of the hollow probe tube;

carrying the debris in the flow of aspiration fluid away from the surgical site;

moving an elastomeric valve member to selectively open and close a fluid flow passageway extending between a source of aspiration fluid and the interior space of the probe tube; and

closing the valve by deforming the elastomeric valve member around any debris in the passageway that would prevent closing of the valve if the elastomeric valve member did not deform.

47. An irrigator/aspirator surgical probe comprising:

a probe assembly comprising a probe body, an elongated hollow probe tube, a spool member, an electrode assembly and a connector;

the probe body includes a housing having an interior chamber, the housing having a bore formed therethrough, the bore extending through the interior chamber of the housing;

the elongated hollow probe tube has an interior space through which irrigation and aspiration fluid flows to and from a surgical site generally at a distal end of the probe tube;

the spool member is connected within the bore of the housing to rotate relative to the housing, the spool member is connected to a proximal end of the probe tube to support the probe tube extending from the spool member, the probe tube rotates in unison with the spool member in the

5

10

15

20

25

30

35

housing, the spool member has an interior channel in fluid communication with the interior space of the probe tube and with the interior chamber of the housing;

the electrode assembly is adapted to be selectively removed from the probe assembly, the electrode assembly comprising an elongated electrode, an electrical connector and an insert;

the elongated electrode is removably positioned within the interior channel of the spool member and extends through the interior space of the hollow probe tube to a distal end from which electrical energy is applied to achieve electrosurgical coagulation at the surgical site;

the electrical connector is connected to a proximal end of the electrode and is accessible at the spool member to conduct electrical energy to the electrode;

the insert is connected adjacent to the proximal end of the electrode and has a retention portion adapted for contacting the spool member and by which retaining force is applied to retain the electrode assembly in position in the probe assembly;

the connector is operatively connected between the spool member and the housing to selectively permit and to selectively prevent rotation of the spool member relative to the housing, the connector further retaining the electrode assembly in position with the electrode extending through the interior channel and the interior space; and

a handle assembly adapted to be gripped to manipulate said probe during a surgical procedure, the handle assembly connected to the probe assembly, the handle assembly comprising a handle, a valve assembly, a locking device and an actuation device;

10

15

20

25

30

35

the handle extending at a predetermined angle from the probe tube and rotatably connected relative to the housing to allow the handle to rotate about an axis extending at the predetermined angle from the probe tube, the handle having a generally hollow interior:

the valve assembly located within the handle and operative for controlling the flow of fluid through the probe tube, the valve assembly comprising a valve body, fluid connection means, an internal passageway, a valve bore, an elastomeric valve member, and means for selectively retaining the valve body;

the valve body is retained in the hollow interior of the handle;

the fluid connection means is adapted for connecting the valve assembly to the source of irrigation or aspiration fluid;

the internal passageway is formed in the valve body and communicates with the source of irrigation or aspiration fluid and with the hollow interior of the probe tube;

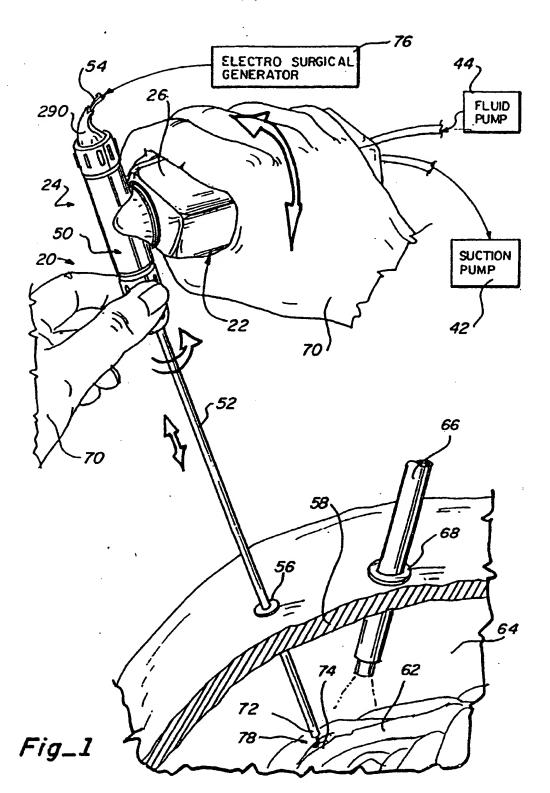
the valve bore is formed in the valve body and intersects the passageway;

the elastomeric valve member is positioned in the valve bore and is moveable to a closed position where the valve member blocks fluid flow through the passageway and is moveable to an open position where the valve member allows fluid flow through the passageway;

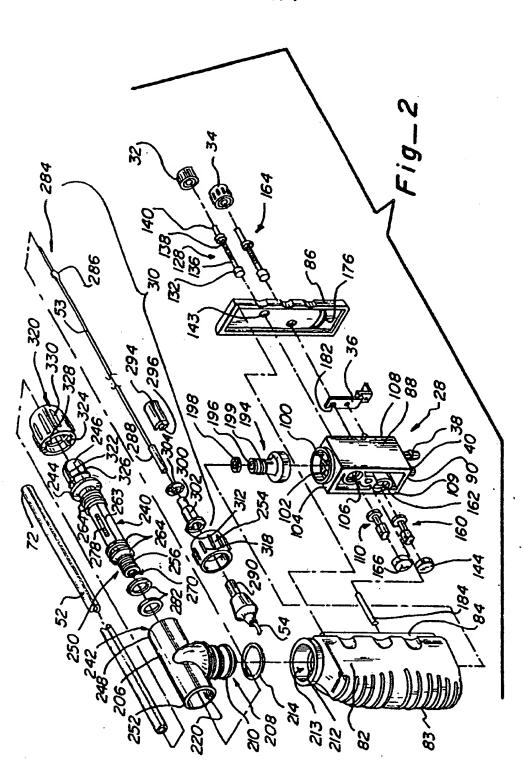
the selective retaining means is connected to the valve body and interacts with the handle for selectively retaining the valve body in position in the handle and for selectively releasing the valve body from the handle for removal of the valve assembly from the surgical probe;

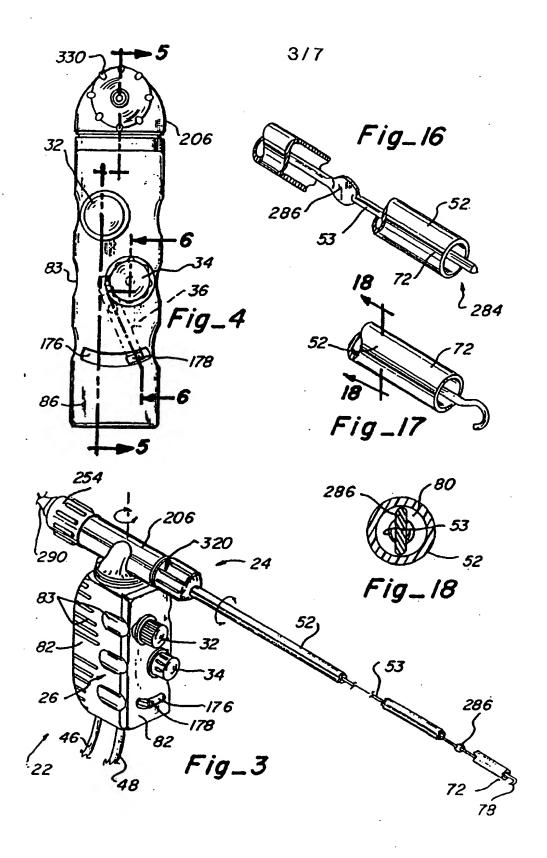
the locking device is connected to the handle and is selectively moveable by the surgeon to hold the valve member in an open position; and

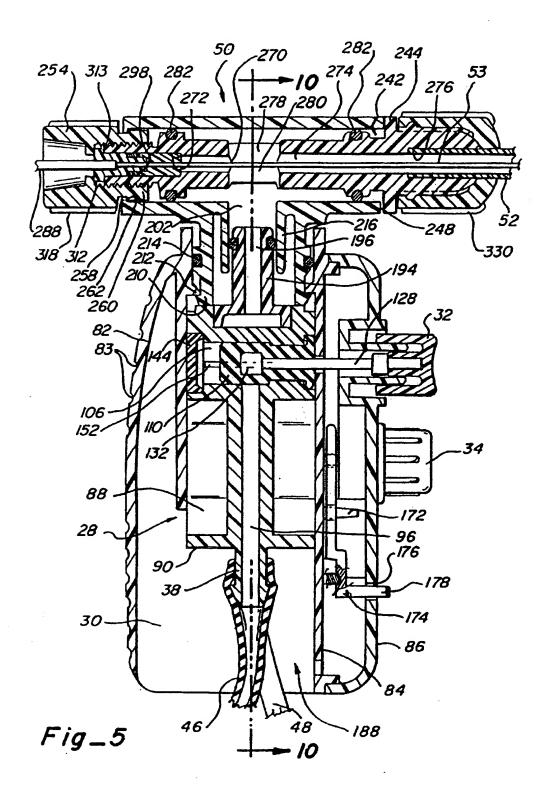
the actuation device is located on the exterior of the handle and is connected to the valve member by which to control the movement of the valve member to the open position.

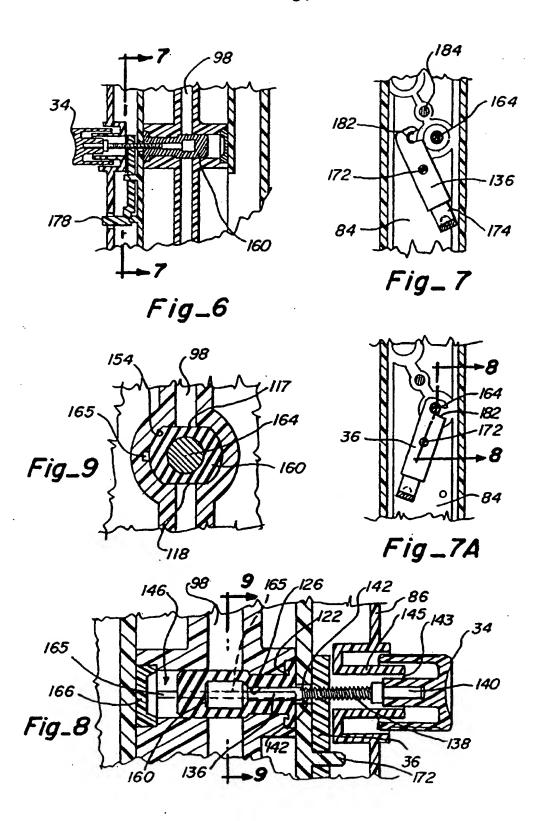


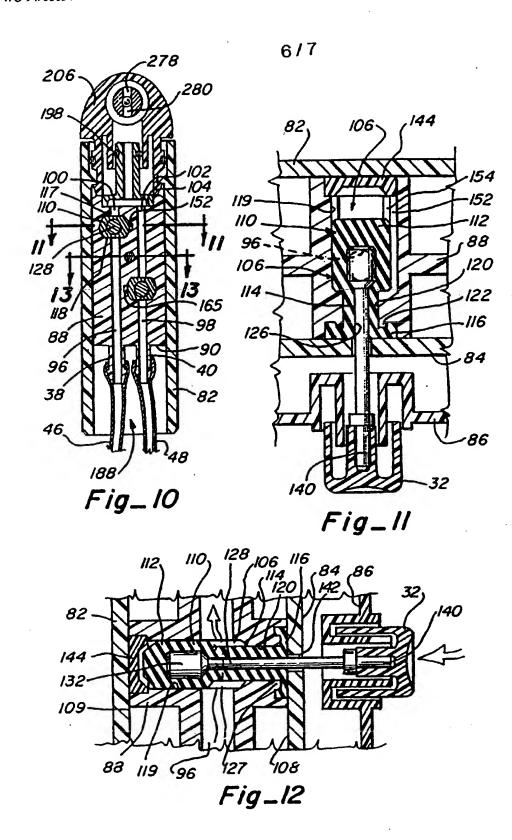




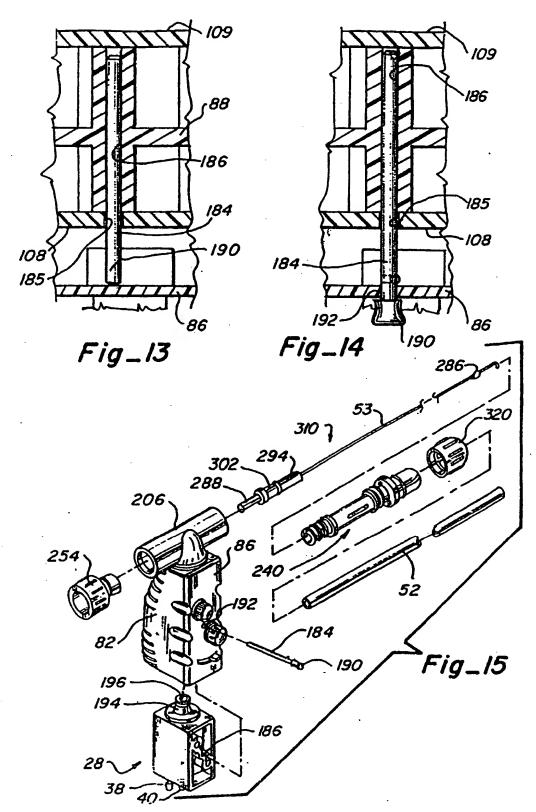








7/7



THIS PAGE BLANK (USPTO)

## This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

BLACK BORDERS

IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

FADED TEXT OR DRAWING

BLURRED OR ILLEGIBLE TEXT OR DRAWING

SKEWED/SLANTED IMAGES

COLOR OR BLACK AND WHITE PHOTOGRAPHS

GRAY SCALE DOCUMENTS

LINES OR MARKS ON ORIGINAL DOCUMENT

REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

## IMAGES ARE BEST AVAILABLE COPY.

☐ OTHER: \_\_\_\_\_

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)